Attachment 10
Environmental Assessment

This information is pertinent to Part IV of FCN No. 663

1. Date: **November 7, 2006**

2. Name of Applicant/Notifier: **Lanxess Deutschland GmbH**

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3. Description of the Proposed Action

a. Requested Action

The action requested in this Food Contact Notification (FCN) is to establish the clearance of the Food Contact Substance (FCS), sulfonic acids, C_{10}-C_{18} alkane, phenyl esters, also known by the tradename Mesamoll II, when intended for use in the fabrication of food-contact articles. Once the FCN becomes effective, the FCS will be used in single service and repeated-use polyvinyl chloride (PVC) articles that may contact aqueous, acidic, low alcohol, and dry foods. The maximum use level of Mesamoll II in the food-contact PVC will not exceed 46% by weight of the finished, plasticized PVC formulation. As the repeated use applications are categorically excluded under 21 C.F.R. § 25.32(j) from the need to prepare an environmental assessment, this environmental assessment addresses only single-use PVC applications.

b. Need for Action

The purpose of the FCS is to plasticize or soften vinyl chloride polymers which are otherwise rigid polymers. Plasticizers reduce molecular binding forces in the polymer and make the polymer more flexible.

c. Location of Use/ Disposal

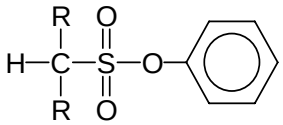
The Notifier does not intend to produce finished food-contact materials; rather, the FCS will be sold to manufacturers and formulators of PVC food-contact articles located at various locations nationwide. PVC food-contact articles produced with the FCS will be utilized in

patterns corresponding to the national population density and it will be widely distributed across the country. Therefore, as PVC film used in food packaging is currently not recycled, it is anticipated that disposal will occur nationwide with the material containing the additive being landfill disposed or combusted. According to the U.S. Environmental Protection Agency's (EPA) 2003 update regarding municipal solid waste in the United States, 55.4% of municipal solid waste generally was land disposed, 14.0% was combusted, and 30.6% was recovered for recycling and composting.[1] Therefore, as the FCS is not expected to be recovered for recycling or for composting, 79.8% of PVC food-contact articles containing the FCS are expected to be disposed in a landfill, while 20.2% is expected to be combusted.[2]

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of PVC employing the subject additive, Mesamoll II.

4. Identification of the Substance that is the Subject of the Proposed Action

The FCS that is the subject of this Notification is a C_{10}-C_{18} alkyl sulfonic acid phenylester. The Chemical Abstracts Service (CAS) Registry Name is "sulfonic acids, C_{10}-C_{18} alkane, phenylesters" and the CAS Reg. No. is 70775-94-9. The FCS is best described as a mixture of isomers with different alkyl chain lengths and mono-, bis-, tris-, and tetra-sulfonated phenylesters of the general chemical structure as presented for the mono-sulfonated phenylester below:



The physical form of the FCS is a liquid.

5. Introduction of the Substance into the Environment

Under 21 C.F.R. § 25.40 (a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal of the substance from its incorporation into food-contact articles, rather than the production of FDA regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of Mesamoll II. Consequently, information on the manufacturing site and compliance with relevant emission requirements are not provided here.

Little or no introduction of the FCS into the environment will result from its incorporation into PVC food-contact articles because the plasticizer, Mesamoll II, is expected to be entirely incorporated into the finished food packaging. As these food-contact articles are produced by a

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[1] *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2003*, EPA 530-F-05-003, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, April 2005.

[2] Landfill waste: 55.4% ÷ 69.4% = 79.8%; Combustible Waste: 14% ÷ 69.4%= 20.2%.

plastics extrusion manufacturing process, Mesamoll II will be added to the PVC resin at the extruder and will be completely incorporated by the extrusion process into the finished PVC article with no discharge of the FCS, *per se,* from the plastics manufacturing process. Any waste materials generated in this process, *e.g.*, PVC scraps, are expected to be recycled into the process or disposed as part of the packaging manufacturer's overall non-hazardous solid waste in accordance with established procedures. Consequently, no introduction of the FCS into the environment will result from the manufacture of the food packaging articles and essentially all of the FCS is expected to remain with the finished articles thoughout use.

Disposal by the ultimate consumer of PVC food-contact articles containing the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen, oxygen, sulfur, and chlorine. The anticipated market volume of the FCS and calculations regarding the maximum introduction levels of sulfur or chlorine containing combustion products are confidential and are included in a confidential attachment to this EA. The Notifier calculates, based on the elemental composition of the FCS, that the potential maximum emissions of HCl and SO_2 combustion products from the FCS will not exceed about 0.005% and 0.2% of their respective emissions from regulated MWC plants reported for year 2000. We conclude that actual emissions are not anticipated to pose an adverse environmental impact resulting from introduction of combustion products from articles containing the FCS. Based on the proposed use of the food-contact substance, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors and, therefore, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 or relevant state and local laws).[3]

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the enivironment as a result of landfill disposal of food-contact articles containing the FCS. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water. These landfills are also required to have ground water monitoring systems (40 C.F.R. Part 258). Although owners and operators of exisiting municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor ground water and to take corrective action as appropriate. Any leaching to the environment is not anticipated considering the low solubility of the FCS in water at 0.002g/L or 2mg/L (2 ppm), thereby severely limiting the migration of the FCS from PVC under aqueous conditions as may be present in a properly operated landfill.

6. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS is in liquid form, but has a high boiling point and does not volatize at temperatures associated with environmental systems.

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[3] *See supra* at note 1.

The vapor pressure is less than 0.0001 hPa at 20°C.[4] Thus, no significant quantities of any substances will be released upon the use and disposal of PVC food-contact articles manufactured with the FCS.

The products of complete combustion of the polymer are carbon dioxide and water, along with small amounts of sulfur dioxide, sulfuric acid, and hydrochloric acid. As discussed above, the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amount utilized for food packaging applications.

(b) Water

No significant effects on the concentrations of, and exposures to, the FCS in fresh water, estuarine, or marine ecosystems, are anticipated due to the proposed use of the subject plasticizer and its proper disposal. No significant quantities of the FCS will be added to these systems upon the proper incineration of the additive, nor upon its disposal in landfills equipped with composite liners and leachate monitoring protocols, especially due to the extremely low levels of aqueous migration of the FCS and its low solubility in water at 0.002 g/L (2 mg/L) at 22°C.

(c) Land

Considering the factors discussed above, no significant effects in the concentrations of, and exposures to, any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS and its proper disposal. In particular, the extremely low levels of maximum migration of components of the FCS, demonstrated by the extraction studies, indicate that very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Furthermore, any leachates that migrate from the discarded food-contact articles will be prohibited from entering adjacent ecosystems by proper environmental controls in place at landfills and incineration sites. Furthermore, the low production of the additive for use in food-contact applications precludes any substantial release to the environment of its components. Thus, there is limited expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

7. Environmental Effects of Released Substances

Considering the foregoing, we respectively submit that there is no reasonable expectation of significant impact on the concentration of the FCS in the environment due to the proposed use of the additive in the manufacture of PVC articles intended for use in contact with food. However, the Notifier realizes that the FCS is able to leach from the PVC food packaging articles in very small quantities and, consequently, the environmental effect of the substances needs to be addressed in those situations where small amounts of the FCS contained in leachate is allowed to migrate to adjacent ecosystems.

Technical formulations of alkyl sulfonic acid phenylesters, such as the FCS (*i.e.*, Mesamoll II), have been used for more than 50 years and are categorized as a so-called HPVC (high

[4] hPa = hectopascals; 0.0001 hPa = 9.87×10^{-8} atm.

production volume chemicals) by the Organization for Economic Cooperation and Development (OECD). They are in use as general-purpose plasticizers for a large range of products based on PVC (polyvinyl chloride), PU (polyurethane) and SBR (styrene- butadiene rubber). Only recently, alkyl sulfonic acid phenyl esters were identified as contaminants in rather high concentrations in sediment samples obtained from the Elbe river, which flows into the North Sea, and its tributaries the Mulde, Havel, and Spree rivers in Germany. Concentration levels of alkyl sulfonic acid phenyl esters in the sediment range from 33,000 µg/kg near the industrial region of Bitterfeld, Germany to 15 µg/kg in sea sediments located near the mouth of the Elbe estuary.[5] The identification of the alkyl sulfonic acid phenylester contaminants was found to be specific to the Elbe River, considered a highly polluted river system due to well known industrial emissions from chemical manufacturing and deficient sewage treatment, and not found in other contaminant river systems discharging into the North Sea.[6]

The finding that the presence of the alkyl sulfonic acid phenyl ester compound is river or waterway specific, indicates that the origin of the vast majority of the material found in the sediment is most likely the result of unregulated chemical and sewage discharge from industrial processes, aggravated by the extremely low solubility of alkyl sulfonic acid phenyl esters at 2 mg/L, which allowed for high concentrations to remain in river sediment. The absence, or non-detection of alkyl sulfonic acid phenyl esters, in additional river systems discharging into the North Sea demonstrates that the origin in the Elbe River is not necessarily originating from alkyl sulfonic acid phenyl esters leaching from food-contact articles, since detection would be expected if migration of these compounds from food-contact and other plastic materials were a widely occurring phenomenon with widespread consequences.

As discussed above, disposal in properly regulated municipal waste landfills and municipal waste combustion plants, coupled with the extremely low solubility of the FCS in water at 0.002 g/L, will prohibit, or at least severely limit, the migration of the FCS to its surrounding environs upon disposal of food articles containing the FCS for its intended use. Although shown to have biodegradable properties, Mesamoll II is classified as not readily biodegradable. In consideration of its biodegradable characteristics, various routes for the decomposition of alkylsulfonic phenyl esters have been reported in the literature.[7]

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of PVC films fabricated with the use of the FCS consist of very small quantities of combustion products and extractables. Toxicology testing has shown the FCS to have no particular alerting toxicological concerns and food-contact articles containing the

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[5] S. Franke, J. Schwarzbauer, and W. Francke, Fresenius J. Anal. Chem., 360, 580-588 (1998), "Arylesters of alkylsulfonic acids in sediments. Part III of organic compounds as contaminants of the Elbe River and its tributaries."

[6] J. Schwarzbauer, R. Littke, and V. Weigelt, Org. Geochem., 31, 1713-1731 (2000), "Identification of specific organic contaminants for estimating the contribution of the Elbe river to the pollution of the German Bight."

[7] J-P. Hinter, P. Fortnagel, S. Franke, W. Francke, and S. Schmidt, Res. Microbiol., 156, 656-662 (2005). "Catabolism of Mesamoll, a technical formulation of alkylsulfonic acid phenyl esters, by two strains of *Rhodococcus rhodochrous*."

FCS are not expected to be a widespread source for its emission to the environment. The results of the ecotoxicity testing confirm the ecological safety of the FCS at the extremely low levels at which it may be present as a result of the disposal of food-contact articles containing Mesamoll II. Based on these considerations, no adverse effects on organisms in the environment are expected as a result of the disposal of articles containing the FCS.

In addition, the use and disposal of PVC food packaging containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 C.F.R. Parts 60 and 258.

8. Use of Resources and Energy

Mesamoll II is intended to compete with and replace other plasticizers used in PVC films for food-contact applications such that there is essentially no effect on the use of natural resources and energy. For example, Mesamoll II is expected to compete with and replace plasticizers that are currently employed in PVC films, such as di(isononyl) adipate and di(2-ethylhexyl) adipate. As is the case with other plasticizers, the production, use, and disposal of Mesamoll II involves the use of natural resources such as petroleum products, coal, and the like. The replacement of currently used plasticizers by Mesamoll II is not expected to have any adverse impact on the use of energy and resources. Manufacture of Mesamoll II and its use in PVC films will consume energy and resources in amounts comparable to the manufacture and use of other plasticizers. Moreover, PVC films containing Mesamoll II are not recovered for recycling, but are disposed of by means of sanitary landfill and incineration. PVC films containing Mesamoll II are expected to be disposed of according to the same patterns when they are used in place of PVC films containing other plasticizers. Thus, there will be no impact on current or future recycling programs.

9. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of PVC food-contact films containing Mesamoll II. This is primarily due to the very small levels of leaching of Mesamoll II from films, the insignificant impact on environmental concentrations of combustion products of Mesamoll II in disposed films, the low ecotoxicity demonstrated by the FCS, and the close similarity of Mesamoll II to plasticizers it is intended to replace. Thus, the use of Mesamoll II as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

10. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein, which would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that Mesamoll II would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of Mesamoll II for use in food-contact films, and the absence of any significant environmental impact that would result from its use, the clearance of the use of Mesamoll II as described herein is environmentally safe in every respect.

11. List of Preparers

William W. Reichert, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

12. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: _____ _____

Devon Wm. Hill
Agent for Lanxess Deutschland GmbH

13. Attachments

Confidential Attachment . . . . . Attachment 12

14. References

The following references are attached to this Environmental Assessment.

S. Franke, J. Schwarzbauer, and W. Francke, Fresenius J. Anal. Chem., 360, 580-588 (1998), "Arylesters of alkyl sulfonic acids in sediments. Part III of organic compounds as contaminants of the Elbe River and its tributaries."

J-P. Hintner, P. Fortnagel, S. Franke, W. Francke, and S. Schmidt, Res. Microbiol, 156, 656-662 (2005). "Catabolism of Mesamoll, a technical formulation of alkylsulfonic acid phenyl esters, by two strains of *Rhodococcus rhodochrous*."

J. Schwarzbauer, R. Littke, and V. Weigelt, Org. Geochem., 31, 1713-1731 (2000), "Identification of specific organic contaminants for estimating the contribution of the Elbe River to the pollution of the German Bight."

Ecotoxicity Studies relevant to the Environmental Assessment provided by the Notifier.